

Application No.: 10/074,272
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REMARKS

Claims 54, 55, 62-78, 80, 81, 83-91, 93-104, 106, 108-112, 114, 116, 117 and 119 are currently pending in this application. Claims 91, 101, 104, 106, 108, 110-112, 114, 116, 117 and 119 are amended herein. Applicants respectfully request reconsideration in view of the above amendments and the following remarks. Pursuant to discussions with the Examiner and to the most recent personal interview, Applicant's attorney is of the understanding that the present amendments made to delete objectionable language under Section 112, second paragraph, would be entered. Similarly, it is Applicant's understanding that the §132 Declaration being submitted herewith will also be entered and given consideration on the merits, since it provides technical information relating to one of the cited references, Strobush. Applicants did not provide this Declaration earlier because, based upon an agreement made at a prior interview, and suggestion by the Examiner, the last amendment was believed to patentably distinguish over the art. It is in the final rejection that Applicants first realized the Examiner was equating the problems in Strobush with the problems addressed by the present invention.

Applicants respectfully point out that the Examiner's statement on page 6, lines 12-13 is incorrect. The Examiner states that Strobush discloses "uniform thickness (Col. 12, lines 27-31) or uniform density, which is without forming aggregates or conglomerates with uniform distribution of components." A review of this passage of Strobush indicates that the Examiner's statement is incorrect. There is no disclosure of uniform thickness, nor mention of formation of the coating without aggregates or conglomerates, nor the mention of forming a uniform distribution of components.

The passage referred to by the Examiner relates only to controlling heat transfer and minimizing disturbances by gas flow to reduce mottle.

Applicants' Response to Double Patenting Rejection

Claim 119 is rejected under the doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 1 of co-pending Application No. 10/768,809 in view of

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U.S. Patent No. 5,044,761 to Yuhki et al. (hereinafter “Yuhki”). Because Application No. 10/768,809 is currently pending, this is a provisional double patenting rejection. Once one of the two respective co-pending applications is in allowable form, Applicants will file a terminal disclaimer, or canceling/amending claims, as necessary. Applicants request the issuance of an *Ex parte Quayle* action if this case is in all other respects found allowable.

Applicants’ Response to 35 U.S.C. §112, Second Paragraph Rejection

Claims 91-104, 106, 108-112, 114, 116, 117 and 119 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. In particular, the Examiner takes the position that the term “slow mixing” in claims 91, 106, 110, 111, 114, 116, 117 and 119 is a relative term, which renders the claims indefinite. Accordingly, claims 91, 106, 110, 111, 114, 116, 117 and 119 have been amended herein to remove the term “slow.” The Examiner also is of the opinion that the term “controlling the mixing speed” in claims 101, 104 and 112 is a relative term, which renders the claims indefinite. Applicants accordingly have amended claims 101, 104 and 112 herein to recite “mixing” in place of “controlling the mixing speed.” The Examiner similarly states that the term “sufficiently slow speed” in claim 108 is a relative term, which renders the claim indefinite. Applicants have amended claim 108 herein to remove the term “sufficiently slow speed.”

In view of the above, Applicants respectfully submit that the Section 112 rejections have been overcome. **Applicants’ Current Claims**

As reviewed at the interview, the pending claims all relate to making a self-supporting, water-soluble, edible film product containing an active, e.g. a drug, nutraceutical, etc. as defined in the specification. The film is not a coating on a substrate, but is its own self-supporting structure. The end product use is an edible film which is to be cut into individual dosage units to deliver an intended dose of active.

One common step to all the claims involves combining water-soluble polymers, water and the active to make a matrix having a uniform distribution of components. A primary

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objective is to make an oral dosage film which has a uniform active content per unit volume of film.

Unlike typical delivery systems for actives such as pills or capsules, the contents of which are fixed in the tablet-punch or within the capsule, the process of manufacturing water-soluble film involves solving the problem of removing water from a flowable matrix without destroying the uniformity of content or destroying the effectiveness of the active. As disclosed throughout Applicant's specification, the uniformity of content refers to having substantially the same amount of active/unit volume throughout the body of the film. Thus, if a relatively thick, wet film one thousand feet long and four feet wide were manufactured according to the inventive process, individual, consumable dosages made from one region on the film would have uniformity of content (substantially the same amount of active/unit volume of film) with individual, consumable dosages from another region in the film. Without uniformity of active/unit volume, the law, as enforced by the Food & Drug Administration, would not permit use or sale of oral dosage forms containing drug. Of course, FDA approval is required to legally sell drug products.

To the best of Applicant's knowledge and belief, obtaining uniformity of active/unit volume in a water-soluble viscous, relatively thick film, has never been accomplished before the invention.

The difficulties in drying a water-based edible film, which remains water-soluble after it dries, and which retains its uniformity of content during the drying process, had not been addressed nor even appreciated by the prior art. Even water-based latex paints are not water-soluble once dried.

Applicant's current claims also contain the common step of "forming a visco-elastic film", prior to the final drying step. Perfection of the visco-elastic film "locks-in" the uniform distribution of components formed in the wet viscous matrix of a prior step.

The formation of the visco-elastic film of this step is accomplished very quickly, usually within a period of four (4) minutes or less, and in many cases within the first minute. See Specification [0147]. The visco-elastic film step is accomplished by driving off water from the bottom-up, while preventing the top of the film from skinning over. As described in the specification, prematurely skinning over the top of the film before the drying depth to form a visco-elastic film causes water leaving the depth of the film to repeatedly rupture the surface, causing random discontinuities and voids in the film, which leads to non-uniformity of active/unit volume of the film.

Additionally, prematurely skimming the top of the film interrupts the thermal mixing which occurs from bottom drying and which keeps the active uniformly suspended.

Rapidly drying from the bottom, while minimizing or having little or no top air flow until a visco-elastic film is formed, has a number of important advantages. Regardless of the active chosen, it is important to minimize its exposure to high temperatures. Thus, rapidly driving off the water from the bottom-up, not only prevents skin-over formation and keeps active uniformly suspended, but minimizes the heat history of the active. Many drugs are heat sensitive and must be stored at room temperature to prevent decomposition. Lengthy exposures to high temperatures during processing, and especially in the presence of water and air, can render them ineffective or even harmful. The invention provides a process, which due to the rapid formation of the film during the visco-elastic formation and drying steps, allows for forming the visco-elastic film rapidly by driving up the solids content at the lower depths of the film prior to top skinning of the film. This step also allows active, which in many cases are large particulates, to remain in suspension. The inventive process takes advantage of bottom-emanating thermal currents, which ultimately form Benard cells, often evidenced by an irregular surface appearance on the film surface, and which provide for internal mixing to keep particles from settling. The step of rapidly forming the visco-elastic film locks-in the uniform distribution of active/unit volume of film before the active can migrate, settle or agglomerate to result in non-uniformity of its distribution within the film.

In addition to the water-solubility of the components and the resultant film made therefrom, and the formation of the visco-elastic matrix by rapidly heating from the bottom prior to skinning over the top, all pending claims also include a deaeration step to remove gases from the mixture. Gaseous inclusions in the film will result in undesirable voids or thinning of the film during the visco-elastic film formation and drying steps. This in turn can result in compositional non-uniformity, i.e., non-uniform amounts of active/volume of the film.

Once the visco-elastic step has been performed by rapidly heating from the bottom, a further step of more fully drying is performed to remove residual moisture in the upper region of the film's thickness. (All pending claims).

Other claims (98, 101-103) contain additional step of dividing the film into dosage forms of equal dimensions, each having compositional uniformity. Pending claims 104 and 106 expressly recite that the water, polymer and active are to be uniformly present in the final film, i.e., the dried film is not "bone" dry but has uniformity of active/unit volume of film. This claim also requires the final dried film to have a uniform weight and thickness.

Claim 106 further requires formation of the wet film within a time before the active degrades.

Claim 110 states the active is a pharmaceutical active and provides for a minimum wet film thickness and no skinning prior to drying the depth of the film.

Claim 116 includes an additional step of adding an anti-foaming agent to help remove air from the film.

Claim 117 includes the steps of forming a masterbatch premix of the edible water-soluble polymer, deaeration by mixing, adding an active and forming a premix having a uniform distribution of components, rapidly forming the visco-elastic film with hot air applied to the

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bottom with substantially no top air flow, further drying the visco-elastic film to form a self-supporting film and removing the film from the drying surface.

Claim 119 captures the concept of forming the visco-elastic film using bottom drying “to prevent air flow migration and intermolecular forces from destroying the uniformity of distribution of components”. This claim language is an alternative expression for “locking-in” the uniformity without skinning or producing disturbances on the top of the film, such as high air flow which would cause uneven film thicknesses to form.

Thus, various aspects of the invention have been captured in the different independent and dependent pending claims.

Applicants' Response to Rejection under 35 U.S.C. §103 over Zerbe in view of Strobush and Yuhki

Claims 91, 93, 97, 100, 101, 106, 108, 109, 111, 112, 114, 117 and 119 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 6,660,292 to Zerbe et al. (hereinafter “Zerbe”) in view of U.S. Patent No. 5,881,476 to Strobush et al. (hereinafter “Strobush”) and Yuhki. Applicants respectfully request reconsideration on the basis that the combination of references is improper and fails to render the claims *prima facie* obvious.

The Examiner asserts that Zerbe discloses a method of forming flavored film. According to the Examiner, the method of Zerbe includes providing a polymer component, flavoring and other ingredients in water for form a solution, coating the solution, or matrix, onto a carrier substrate, drying the film with hot air and removing the film after drying. Zerbe, however, teaches nothing more than generally drying the film. The Examiner accordingly admits that Zerbe fails to disclose applying hot air to the bottom of the substrate with substantially no top air flow to dry the film and rapidly form a viscoelastic film. The Examiner also recognizes that Zerbe fails to disclose drying the film in a manner that prevents air flow migration and intermolecular forces from forming aggregates or conglomerates to maintain compositional

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uniformity. Additionally, the Examiner acknowledges that Zerbe fails to disclose deaerating the matrix by slow mixing.

The Examiner, however, asserts that:

...directing hot air to the bottom of the substrate with a higher air current at the bottom than the top or substantially no top air flow to dry the film is well known and conventional as shown for example by Strobush et al. (Action, page 6)

According to the Examiner, Strobush teaches “providing a substrate with a coating applied to a coating to a substrate, feeding the coated substrate into a drying apparatus, in which air foils are located below the coated substrate that direct drying gas to the bottom surface of the substrate with air bars to supply top-side air to dry the coated substrate “without mottle defects, i.e. uniform thickness or uniform density, which is without forming aggregates or conglomerates with uniform distribution of components.” (Action, page 6)

The Examiner concludes that:

It would have been obvious to one of ordinary skill in the art at the time the invention was made to dry the coating on a substrate by directing drying gas to the bottom of the coated substrate as disclosed by Strobush et al in the method of Zerbe et al ('292) to dry the coating on a substrate without mottle and at higher web speeds.

The Examiner's assertions are respectfully traversed.

It is respectfully submitted that Zerbe, Strobush and Yuhki do not together form a proper rejection of claims 91, 93, 97, 100, 101, 106, 108, 109, 111, 112, 114, 117 and 119 for at least the following reasons. First, Strobush is nonanalogous art and is not properly useable in formulating a rejection of the claims herein. Second, there is no motivation to combine Zerbe

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and Strobush as suggested by the Examiner. Third, there is no reasonable expectation of success and, accordingly, there is no *prima facie* showing of obviousness based on this hypothetical combination.

1. **Strobush is nonanalogous art**

If a reference is “nonanalogous art,” it cannot be relied upon as a basis for rejecting an applicant’s claims. As set forth in the case law, there are two criteria for determining whether or not a prior art reference is “analogous”:

(1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.

In re Clay, 966 F.2d 656, 658-59, 23 U.S.P.Q.2d 1058, 1060-61 (Fed. Cir. 1992); *see also In re Oetiker*, 977 F.2d 1443, 1447, 24 U.S.P.Q.2d 1443, 1445 (Fed. Cir. 1992); *In re Deminski*, 796 F.2d 436, 442, 230 U.S.P.Q. 313, 315 (Fed. Cir. 1986).

A reference is only “reasonably pertinent” if it is one which “logically would have commended itself to an inventor’s attention in considering his problem.” *In re Clay*, 966 F.2d at 659.

As the court further explained in *In re Oetiker*:

Patent examination is necessarily conducted by hindsight, with complete knowledge of the applicant’s invention, and the courts have recognized the subjective aspects of determining whether an inventor would reasonably be motivated to go to the field in which the examiner found the reference, in order to solve the problem confronting the inventor. We have reminded ourselves and the PTO that it is necessary to consider ‘the reality of the circumstances’ - in other words, common sense - in deciding in

which fields a person of ordinary skill would reasonable be expected to look for a solution to the problem facing the inventor.

In re Oetiker, 977 F.2d at 1447 (citations omitted).

In accordance therewith, MPEP §2141.01(a) similarly expresses the standard that only references that relate to the field of an inventor's endeavor or that are reasonably pertinent to the particular problem to which an inventor is concerned with may be relied upon in formulating a rejection. Strobush is outside the inventors' field of endeavor and is not at all concerned with the particular problems with which the inventors herein were concerned. Strobush relates only to the problem of solving mottle in highly volatile organic solvent-based image coatings, which as indicated in the Declaration Under 37 C.F.R. §1.132 by Dr. Rhyta Rounds submitted herewith (hereinafter the "Rounds Declaration"), is an entirely different and unrelated problem than the problems addressed by the present invention.

As indicated in the specification of the present application, for example at page 4, paragraph 10, the inventors were concerned with forming ingestible films that can be divided into equally sized dosage units having substantially equal amounts of each compositional component present. The dosage units include a significant component, i.e., a drug or other active as defined in the specification. Hereinafter, the significant component will be referred to as "Active". The inventors were particularly concerned with forming ingestible films for use as pharmaceutical dosage delivery systems in which each dosage unit, e.g., each individual dosage film unit, contains the proper amount of Active, as explained on page 4, paragraph 10 of the specification. As further explained in the specification at page 2, paragraph 4, the prior art has been unsuccessful in providing individual film dosage units containing the proper amount of Active, which is necessary for satisfying federal regulatory requirements for making a commercial product.

The problem of providing compositionally uniform films for use as oral dosage units, with which the subject inventors were concerned, involves solving a number of different

technical problems, none of which relate to mottle. As indicated in the Rounds Declaration, achieving such uniform film products involves overcoming a variety of technical difficulties due to the relatively large size of active particles, the irregular shape of active particles, the ability to maintain the particles in dispersion without falling out of solution, the use of aqueous-based systems, and external forces, among others. *See* Rounds Declaration, paragraphs 19-20 and 23-25. Random air voids, Active (e.g. drug) component particle migration and Active component particle aggregation are just some of the resultant problems experienced in such systems. *See* Rounds Declaration, paragraph 25. As asserted by Dr. Rounds, obtaining compositionally uniform products is critical for drug-containing films. *See* Rounds Declaration, paragraphs 18 and 27.

In contrast, Strobush is directed to an apparatus and method for producing non-ingestible photothermographic, thermographic and photographic coatings on a substrate without mottle. Mottle is the sole problem addressed by Strobush. As set forth in the accompanying declaration, Strobush is concerned with surface defects of the coated substrate because they would detract from the appearance of the finished product, e.g. a photograph. *See* Rounds Declaration, paragraphs 10-11 and 17. Mottle is a serious problem in Strobush because its thin (sub-millimeter) coatings are emulsion systems composed of very small silver particles dissolved in highly volatile non-aqueous solvents. *See* Rounds Declaration, paragraphs 12-14. Such problem is addressed by using a complex drying apparatus, which includes a sequence of zones, to control the factors leading to mottle. *See* Rounds Declaration, paragraphs 15-16. The method of preparing the coated substrates of Strobush therefore involves very different chemical systems and criteria than the systems and objectives sought by the inventors herein. *See* Rounds Declaration, paragraphs 21-26.

It is clear that the inventors herein seeking to satisfy the problems associated with ingestible film dosage units would not look to Strobush. Strobush is concerned with the surface appearance of a coated substrate used in making non-ingestible imaging articles -- properties which play no part in solving the technical problems of the present invention. Indeed, as stated

in the declaration, “surface imperfections in the inventive films are expected.” *See* Rounds Declaration, paragraph 25. Contrary to the Examiner’s assertions, mottle, which is the problem addressed in Strobush, is wholly unrelated to the problem of achieving compositionally uniform film dosage units for oral administration of actives. *See* Rounds Declaration, paragraphs 21-26.

Therefore, not only is Strobush not in the field of the inventors’ endeavor, Strobush is not at all relevant to the problem with which the present inventors were concerned. In considering the inventors’ specific problem of providing ingestible films that can be divided into equally sized dosage units having substantially equal amounts of each compositional component present, one skilled in the art would not look to Strobush. For all the reasons stated above, Strobush is not analogous art and can not be properly relied upon in formulating any rejection herein.

2. No motivation to combine Zerbe and Strobush

As set forth in MPEP §2143.01, “Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art.”

Contrary to the Examiner’s assertions, there is no motivation to combine Zerbe and Strobush. Zerbe relates to rapidly disintegrating flavored films. The films are used to flavor food items, such as hamburgers or pizza. The films include a mixture of hydroxypropyl cellulose and modified starch, and a flavor ingredient. Zerbe only generally mentions drying the films and uses conventional hot air ovens to do so. Zerbe does not suggest that any concerns are raised by such conventional drying and based on his disclosure, one of ordinary skill in the art would assume there are no problems to be overcome. In fact, Zerbe discusses drying as if it is merely incidental to his invention and can be accomplished without overcoming any technical problems whatsoever. Therefore, Zerbe provides no reason or suggestion to look to any other art

for a different method of drying its film products. Zerbe teaches the skilled artisan that conventional oven drying is sufficient to dry films.

In contrast, Strobush, as discussed above, is directed to non-ingestible coated substrates used in producing imaging articles. Strobush's systems contain small silver particles dissolved in volatile, toxic non-aqueous solvents that evaporate rapidly. Such rapid evaporation can lead to surface defects in Strobush's systems. This is an entirely different technical field of endeavor from the formation of edible film products, such as Zerbe's films, involving completely different chemistry and processing considerations. *See* Rounds Declaration, paragraph 21-26. There would be no motivation for one of ordinary skill in Zerbe's field of art to look to such a wholly unrelated technical area for processing edible films.

Moreover, the purpose of Strobush is to reduce mottle, or surface defects in the appearance of the coated substrate. Surface appearance, however, is not typically a problem in edible film products. As such, there additionally would be no motivation for one skilled in Zerbe's field of art to look to Strobush because the primary objective of Strobush is not germane to edible film processing.

Therefore, there is no suggestion in Zerbe itself to look to any other art, particularly unrelated art such as Strobush, for methods of drying its edible film products. Moreover, there would be no motivation from one skilled in the art's general knowledge to look to such an unrelated area of technology for processes useful in forming edible film products. Therefore, it is respectfully submitted that no motivation is present to combine Zerbe and Strobush as suggested by the Examiner. The Examiner's obviousness rejection requires a combination of three cited references. Because there is no motivation to combine at least two of the three references, no *prima facie* showing of obviousness has been made.

3. **Strobush Coating Process Teaches Away From Water-Based Ingestible Self-Supporting Films**

The differences between the inventive process and Strobush go even well beyond the fact that they are entirely different technologies. In fact, Strobush makes permanent coatings on a substrate. This is in contrast to the self-supporting, edible structures of the invention. The two processes are in fact diametrically opposed in many respects. *See* Rounds Declaration, paragraphs 27-28, where many of the differences are juxtaposed in a table. The Strobush patent mentions application of heat to the bottom of the coated substrate to dry and permanently attach the photographic emulsion layers thereto. However, the mention of bottom drying is part of a complicated drying apparatus with multiple zones and sub zones by which he incrementally controls the temperature differential between his single monolayer of silver particles and the drying environment. By minimizing the $h\Delta T$ in these zones, he is able to very slowly remove the highly volatile organic solvent (2-butanone, also known as MEK), with a minimum disturbance of the silver particles. Strobush's goal is to align the silver particles as flat and evenly as possible on the surface of the photographic paper such that when the photographic film is exposed to light and developed, surface defects in the image, i.e., mottle, is minimized. Rather than ramping up the temperature quickly, as in the present invention, Strobush does the opposite. In fact, he uses a drying apparatus which is about 100 feet long (30 meters) to slowly dry.

Strobush does not simply use bottom drying. He uses it along with top air and ventilation systems to remove the volatile, toxic fumes from the multiple heating zones. Thus, taking only the bottom drying disclosure from Strobush and applying it to a totally different type of technology, i.e., a water-based, edible film, is picking and choosing an element from the reference without giving consideration to its full teachings. Bottom drying in Strobush cannot be separated from the multi-zoned and sub-zone heating areas which are required to slowly evaporate the solvent to leave behind surface aligned silver particles. The thrust of Strobush is the incremental temperature differential between his many zones. In figure 20, he indicates the

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presence of 15 zones (drying gas temperatures) where the temperature differential is minimized to keep down mottle formation.

Strobush is drying a colloidal dispersion of silver particles in MEK. Such a dispersion behaves very differently than suspensions of macroparticles, such as those of the invention. *See* Rounds Declaration, paragraph 25. Thus, Strobush's process of drying to achieve a permanent coating is not in any way comparable to the invention and in fact is contrary to the invention. Whereas the invention claims rapidly forming a visco-elastic film to lock-in uniformity, Strobush teaches to very slowly change the temperature through a series of zones and is completely silent as to rheology or the formation of a visco-elastic film. It is also unlikely that such a visco-elastic film would form given the materials Strobush uses.

At the interview, the Examiner raised Strobush's statement in Column 9, lines 9-12.

While suitable for a wide variety of coatings, the drying apparatus 10 is particularly suited for drying photothermographic and thermographic coatings to prepare photothermographic and thermographic articles.

There are at least two points to be made here. First, regardless of other types of coatings, he uses his apparatus for, the only problem he seeks to solves is mottle. Second, there is no mention of water in Strobush, with the exception of Col. 3, line 59 and Col. 4, line 1, where he distinguishes the problems of prior art water-based systems from his solvent systems. Thus, a fair reading of this statement cannot be that one could switch to a water-based solvent system.

Furthermore, Strobush even states that drying water-based latex paint coatings solves an entirely different problem from mottle. Thus, even permanent coatings of water-based paint is not seen to Strobush to be relevant to his process. The inventive, self-supporting edible water-soluble films would clearly be even further from the Strobush process. It is totally unclear what

would motivate one of ordinary skill in the art to look to the solvent based photographic art, much less the process of Strobush.

It is also relevant that Zerbe '292 requires water as the solvent. The polymers and film-forming agents must be water-soluble or water-swellable respectively. *See* Col. 4, lines 4-5 and Col. 4, lines 59-61. Additionally, Zerbe '957 specifically requires the "solvents must be acceptable for food, food service, cosmetic and pharmaceutical products." Col. 4, lines 4-5. To use an organic-solvent based process in the water-based systems of Zerbe, would destroy the intent and purpose of Zerbe. Similarly, to extract only the bottom drying disclosure from the solvent-based systems of Strobush would destroy the intent and purpose of Strobush. On this basis alone, the references should not be combined.

The present claims also contain a deaeration by mixing step, during which gas is removed from the film composition mixture. This step would be contrary to using a Strobush process, since this rapidly removes his volatile organic solvent and defeats his purpose. In fact, deaeration may create a dangerous, explosive situation. The teachings of the tertiary reference Yuhki (water-based) which respect to deaeration are contrary to Strobush and such divergent teachings are not properly combinable.

4. No reasonable expectation of success

As set forth in MPEP §2143, to establish a *prima facie* case of obviousness, there also must be "a reasonable expectation of success."

Not only is there no suggestion to combine the teachings of Zerbe and Strobush, as discussed above, there is no reasonable expectation of success that the hypothetical combination would work. As set forth above, Zerbe and Strobush relate to completely different chemical systems, which involve different processing considerations. Zerbe uses a hot air oven to dry its edible film products. Strobush meanwhile teaches a complex drying method, in which a number

of sequential drying zones are employed. The entire objective of Strobush is to reduce mottle, i.e., surface defects in its coated substrates, which is a significant problem in Strobush's systems, as discussed above. There is no indication in Zerbe that mottle is a problem in its edible film products. Therefore, not only are the compositional make-up of the systems disclosed in Zerbe and Strobush disparate, but the problems experienced in forming such products are entirely different. One skilled in the art would have no reason to expect that the drying process taught in Strobush for reducing mottle in highly volatile organic solvent-based image coatings could be applied to Zerbe's aqueous-based edible compositions to produce dried, edible films.

Use of the Zerbe aqueous-based compositions with the Strobush teachings would not be expected to produce the products of the invention. That is, the amount of Active in each dose would not be expected to be predictable and compositional uniformity would not be obtained.

See Rounds Declaration, paragraph 27.

Therefore, there is no reasonable expectation of success that the process of sequential drying taught in Strobush could be used with Zerbe's compositions to produce dried films without destroying the active, e.g., flavor, contained therein. Moreover, there is no reasonable expectation of success that such hypothetical combination could produce an edible film having a uniform distribution of components throughout such that it could be divided into individual dosage units having the same amount of Active in each unit, as recited in Applicants' claims. Because there is no reasonable expectation of success based on the hypothetical combination of references, no *prima facie* showing of obviousness has been made.

In view of the above remarks, it is respectfully submitted that claims 91, 93, 97, 100, 101, 106, 108, 109, 111, 112, 114, 117 and 119 are patentable over Zerbe, Strobush and Yuhki, each taken alone or in combination.

Applicants' Response to Rejections under 35 U.S.C. §103 over Zerbe in view of Strobush, Yuhki and Horstmann

Claims 94 and 95 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Zerbe in view of Strobush, Yuhki and U.S. Patent No. 5,629,003 to Horstmann et al. (hereinafter "Horstmann"). Applicants respectfully request reconsideration on the basis that the combination of references is improper and fails to render the claims *prima facie* obvious.

Claims 94 and 95 depend from claim 91, and thus, require all of the limitations of claim 91. As discussed in detail above with regard to claim 91, Strobush is not properly useable in formulating a rejection of the claims, and additionally, the Examiner has not met the requirements for a *prima facie* showing of obviousness based on the combination of Zerbe, Strobush and Yuhki. Moreover, Horstmann was cited merely for its disclosure relating to film thickness and contains no disclosure of relevance to Applicants' process of forming edible films having compositional uniformity. Horstmann, therefore, fails to cure the deficiencies of Zerbe, Strobush and Yuhki. As such, it is respectfully submitted that claims 94 and 95 are patentable over Zerbe, Strobush, Yuhki and Horstmann, each taken alone or in combination.

Applicants' Response to Rejection under 35 U.S.C. §103 over Zerbe in view of Strobush, Yuhki and Wittwer

Claim 96 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Zerbe in view of Strobush, Yuhki and U.S. Patent No. 4,478,658 to Wittwer (hereinafter "Wittwer"). Applicants respectfully request reconsideration on the basis that the combination of references is improper and fails to render the claim *prima facie* obvious.

Claim 96 depends from claim 91, and thus, requires all of the limitations of claim 91. As discussed with regard to claim 91, Strobush is not properly useable in formulating a rejection of the claims, and additionally, the Examiner has not met the requirements for a *prima facie* showing of obviousness based on the combination of Zerbe, Strobush and Yuhki. Wittwer was cited merely for its disclosure relating to film viscosity. Wittwer contains no disclosure of

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relevance to Applicants' process, and thus, fails to cure the deficiencies of Zerbe, Strobush and Yuhki in this regard. Therefore, it is respectfully submitted that claim 96 is patentable over Zerbe, Strobush, Yuhki and Wittwer, each taken alone or in combination.

Applicants' Response to Rejection under 35 U.S.C. §103 over Zerbe in view of Strobush, Yuhki and Zerbe '957

Claims 98, 99, 102 and 103 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Zerbe in view of Strobush, Yuhki and U.S. Patent No. 6,231,957 to Zerbe et al. (hereinafter "Zerbe '957"). Applicants respectfully request reconsideration on the basis that the combination of references is improper and fails to render the claims *prima facie* obvious.

Claims 98 and 99 depend from claim 91, and thus, require all of the limitations of claim 91. Claims 102 and 103 depend from claim 101, and thus, require all of the limitations of claim 101. Again, as discussed in detail above with regard to claims 91 and 101, Strobush is not properly useable in formulating a rejection of the claims, and additionally, the Examiner has not met the requirements for a *prima facie* showing of obviousness based on the combination of Zerbe, Strobush and Yuhki. Moreover, Zerbe '957 was cited merely for its disclosure relating to cutting film into pieces and packaging the films into containers. Zerbe '957 contains no disclosure of relevance to edible films having compositional uniformity, nor processes for achieving such films. Zerbe '957, therefore, fails to cure the deficiencies of Zerbe, Strobush and Yuhki in this regard. In view thereof, it is respectfully submitted that claims 98, 99, 102 and 103 are patentable over Zerbe, Strobush, Yuhki and Zerbe '957, each taken alone or in combination.

Applicants' Response to Rejections under 35 U.S.C. §103 over Zerbe in view of Strobush, Yuhki and Horstmann

Claims 104 and 110 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Zerbe in view of Strobush, Yuhki and Horstmann. Applicants respectfully request reconsideration on the basis that the combination of references is improper and fails to render the claims *prima facie* obvious.

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Independent claims 104 and 110 require at least the same general process limitations as claim 91. As discussed in detail above with regard to claim 91, Strobush is nonanalogous art, and thus, not properly useable in formulating a rejection of the claims herein. Additionally, as explained with regard to claim 91, there is no motivation to combine Zerbe and Strobush, as well as no reasonable expectation that the hypothetical combination would work. These arguments are similarly applicable to claims 104 and 110 and for the sake of brevity are not repeated herein.

Therefore, the Examiner has failed to establish a *prima facie* showing of obviousness based on the combination of Zerbe, Strobush and Yuhki. Moreover, Horstmann was cited merely for its disclosure relating to film thickness and contains no disclosure of relevance to Applicants' process of forming edible films having compositional uniformity. Horstmann, therefore, fails to cure the deficiencies of Zerbe, Strobush and Yuhki in this regard. In view thereof, it is respectfully submitted that claims 104 and 110 are patentable over Zerbe, Strobush, Yuhki and Horstmann, each taken alone or in combination.

Applicants' Response to Rejection under 35 U.S.C. §103 over Zerbe in view of Strobush, Yuhki and Mehra

Claim 116 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Zerbe in view of Strobush, Yuhki and U.S. Patent No. 5,733,575 to Mehra et al. (hereinafter "Mehra"). Applicants respectfully request reconsideration on the basis that the combination of references is improper and fails to render the claim *prima facie* obvious.

Independent claim 116 requires at least the same general process limitations as claim 91. As discussed in detail above with regard to claim 91, Strobush is nonanalogous art, and thus, not properly useable in formulating a rejection of the claims herein. Additionally, as explained with regard to claim 91, there is no motivation to combine Zerbe and Strobush, as well as no reasonable expectation that the hypothetical combination would work. These arguments are similarly applicable to claim 116 and for the sake of brevity are not repeated herein. Moreover, Mehra was cited merely for its disclosure of anti-foaming agents and fails to include any

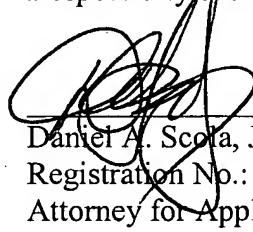
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disclosure of relevance to Applicants' recited process steps. Mehra, therefore, fails to cure the deficiencies of Zerbe, Strobush and Yuhki in this regard. Therefore, it is respectfully submitted that claim 116 is patentable over Zerbe, Strobush, Yuhki and Mehra, each taken alone or in combination.

As such, claims 91, 93-104, 106, 108-112, 114, 116, 117 and 119 are believed to be in proper form for allowance. A favorable reconsideration of the application on the merits is earnestly solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

Respectfully submitted,



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